



DEPARTMENT OF COMMERCE
Foreign-Trade Zones Board
[B-21-2021]

Foreign-Trade Zone (FTZ) 99 – Wilmington, Delaware
Notification of Proposed Production Activity
AstraZeneca Pharmaceuticals LP
(Pharmaceutical Products)
Newark, Delaware

AstraZeneca Pharmaceuticals LP (AstraZeneca) submitted a notification of proposed production activity to the FTZ Board for its facility in Newark, Delaware. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on March 11, 2021.

AstraZeneca already has authority to produce certain pharmaceutical products within Subzone 99D. The current request would add finished products and foreign status materials to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status materials and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt AstraZeneca from customs duty payments on the foreign-status materials/components used in export production. On its domestic sales, for the foreign-status materials/components noted below and in the existing scope of authority, AstraZeneca would be able to choose the duty rates during customs entry procedures that apply to: CALQUENCE (acalabrutinib) capsules; DAKLINZA (daclatasvir) tablets; FARXIGA\FORXIGA (dapagliflozin) tablets; KOMBIGLYZE IR (metformin hydrochloride and saxagliptin hydrochloride) tablets; KOMBIGLYZE XR (metformin hydrochloride and saxagliptin hydrochloride) tablets; METFORMIN IR (metformin hydrochloride) tablets; ONGLYZA (saxagliptin hydrochloride) tablets; QTERN (dapagliflozin and saxagliptin hydrochloride) tablets;

QTERNMET XR (dapagliflozin, metformin hydrochloride and saxagliptin hydrochloride) tablets; TAGRISSO (osimertinib mesylate) tablets; XIGDUO IR (dapagliflozin and metformin hydrochloride) tablets; XIGDUO XR (dapagliflozin & metformin hydrochloride) tablets; and, CRESTOR (rosuvastatin calcium) tablets (duty-free). AstraZeneca would be able to avoid duty on foreign-status components which become scrap/waste. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The materials sourced from abroad include: metformin hydrochloride active pharmaceutical ingredient (API); dapagliflozin API; daclatasvir API; osimertinib mesylate API; acalabrutinib API; saxagliptin hydrochloride API; rosuvastatin calcium API; and, microcrystalline cellulose (duty rate ranges from 3.7% to 6.5%). The request indicates that certain materials are subject to duties under Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is **[INSERT DATE 40 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

A copy of the notification will be available for public inspection in the "Reading Room" section of the Board's website, which is accessible via www.trade.gov/ftz.

For further information, contact Christopher Wedderburn at Chris.Wedderburn@trade.gov.

Dated: March 15, 2021.

Andrew McGilvray,
Executive Secretary.

